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Docket No. IMED-0010-USReply to Office Action dated June 28, 2005**REMARKS/ARGUMENTS**

Favorable reconsideration of this application in light of the following discussion is respectfully requested.

Claims 1-23, 28 and 30-33 are presently active in this case. The present Amendment amends Claims 1, 2, 28 and 30. The above amendment shows the amended claims in marked up form for the Examiner's convenience.

In the outstanding Office Action, claims 2-13, 32 and 33 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 4, 5, 14-18, 20-23, 28, 30 and 31 were rejected under 35 U.S.C. 102(b) as being anticipated by Strickland et al. (U.S. Patent No. 6,679,265). Claims 2, 3, 6-13, 19, 32 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Strickland et al. (U.S. Patent. No. 6,679,265).

In response to the rejection under 35 U.S.C. 112, first paragraph, of Claims 2-13 and 32-33, Applicant directs the Examiner to Fig. 2 and paragraphs 12 and 32-33 of the Specification. In response to the argument that the specification does not provide support for "the first, second and third portions of the input gas flow passage being disposed at an obtuse angle," paragraph 12, lines 3-4 states, "The first and second portions of the input gas flow passage are disposed at an obtuse angle to one another," where the first portion of input gas flow passage is defined as cannula 300 and nasal inserts 120 are defined to be the second portion in paragraph 32, lines 20-24. Further, paragraph 32, with reference to Fig. 2, states, "The first 141 and second 123 portions of the input gas flow passage are disposed at an obtuse angle to one another." Paragraph 33 goes on to state, "the obtuse angle is between about 110° and about 170°, and more preferably the obtuse angle is about 135°." Additionally, with respect to Fig. 2, it

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is clearly shown that the at least one nasal inserts described as second and third portions of the input gas flow passage in claim 1 are disposed at an obtuse angle to the first input gas flow passage.

With respect to the argument that the "first portion of an input gas flow passage being oriented in a downward fashion connected to a feed tube," Applicant directs the Examiner to Figs. 1-6. Figs. 1-6 show the first portion of an input gas flow passage being oriented in a downward fashion. Specifically, in Fig. 1, when second and third portions of the input gas flow passage are inserted into the nares of a user, the substantially axially aligned first portion of the gas flow passage will have its opening disposed substantially opposite those of the second and third portions of the input gas flow passage, in a downward fashion. Further, as shown in Fig. 1 and in paragraph 38, lines 9-10, first portion of an input gas flow passage can include "a distal end 142 to the source of ventilation gas via a feed tube 500, 600." Therefore it is believed that claims 2-13, 32 and 33 comply with 35 U.S.C. 112, first paragraph.

In response to the rejection(s) of Claims 1-23, 28 and 30-33 under 35 U.S.C. 102(e) and 35 U.S.C 103(a), Applicants have amended claims 1, 2, 28 and 30 and respectfully request reconsideration of these rejections and traverse the rejections as discussed next.

Briefly recapitulating, Applicants' invention relates to a ventilation or CPAP interface system adapted to be inserted into a nares of a user to secure the interface. As explained in Applicants' specification at page 7, lines 31-57 with corresponding Figs. 1-12, Applicants' invention, therefore, improves upon conventional ventilation and CPAP interface systems. The claimed invention thus leads to improved ventilation and gas flow in a ventilation or CPAP interface.

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Turning now to the applied prior art, the Strickland et al patent discloses a nasal cannula having poor laminar gas flow qualities due to the orientation of the nasal inserts to the nasal cannula.

**102 fail to teach or suggest every limitation**

Claims 1, 4, 5, 14-18, 20-23, 28, 30 and 31 stand rejected under 35 U.S.C. 102(e) as being anticipated by Strickland et al. (U.S. Patent No. 6,679,265). Pursuant to the interview with the Examiner, independent claims 1, 28 and 30 have been amended to show that the distal ends of the cannula where the cannula is connected to a ventilation source are substantially axially aligned with the nasal inserts. During the interview and follow up phone calls, it was indicated by the Examiner that the "first portion of an input gas flow passage," described in unamended independent claims 1, 28 and 30 was not clearly indicative of the end portions of the cannula where the cannula connects to a source of ventilation gas. Thus, during the final telephone conversation, it was decided to include the language regarding the first portion of the input gas flow passage defined by the first and second passages being disposed at the distal ends of the cannula where the cannula connects to a source of ventilation gas. This language differentiates the portions of the first input gas flow passage that are substantially axially aligned with the nasal inserts from other portions of the first input gas flow passage.

Specifically, claim 1 now states, "the first portion of the input gas flow passage defined by a first passage disposed at a first distal end of the cannula where the cannula is connected to a first source of ventilation gas and a second passage disposed at a second distal end of the cannula where the cannula is connected to a

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second source of ventilation gas;" and, "the at least one nasal insert forming second and third portions of the input gas flow passage from the cannula to a distal end of the nasal insert that are substantially axially aligned with the first passage disposed at the first distal end of the cannula where the cannula is connected to a first source of ventilation gas and the second passage disposed at the second distal end of the cannula where the cannula is connected to the second source of ventilation gas."

Claim 28 now states, "means for forming a first input gas flow portion having input gas flow passages disposed at distal ends of the first input gas flow portion where the first input gas flow portion connects to a source of ventilation gas, the input gas flow passages being substantially axially aligned with a second portion of the input gas flow passage."

Claim 30 now states, "the cannula is adapted to be connected to the first feed tube, second feed tube and Y-connector, the cannula forming a first portion of an input gas flow passage, the first portion of the input gas flow passage defined by a first passage that connects to the first feed tube and a second passage that connects to a second feed tube," and, "the first passage and the second passage of the input gas flow passage being substantially axially aligned with the nasal inserts."

Support for the new features in claims 1, 28 and 30 may be found in the specification, for example, in paragraphs [0034], [0038] and [0039], as well as in the figures, for example, figure 6.

With respect to independent claims 1, 28 and 30, the Strickland et al. patent fails to teach a first passage and a second passage disposed at the distal ends of a cannula where the cannula connects to a source of ventilation gas are substantially axially aligned with the at least one nasal insert as in independent claims 1, 28 and 30. On the

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contrary, Strickland et al explicitly teaches that a first portion of an input gas flow passage where the cannula is connected to a source of ventilation gas is substantially perpendicular with the nasal inserts.<sup>1</sup> In view of the above, the cited prior art fails to teach or suggest every feature recited in Applicants' claims, so that Claims 1, 28 and 30 are believed to be patentably distinguishable over the cited prior art. Accordingly, Applicants respectfully traverse, and request reconsideration of, the rejections based on Strickland et al.<sup>2</sup>

**103 fail to teach or suggest every limitation**

Claims 2, 3, 6-13, 19, 32 and 33 stand rejected under 35.U.S.C. 103(a) as being unpatentable over Strickland et al. (U.S. Patent No. 6,679,265). This rejection is respectfully traversed for the reasons stated above. Further, claim 2 has been amended to state, "first portion of the input gas flow passage defined by a first passage disposed at a first distal end of the cannula where the cannula is connected to a first source of ventilation gas and a second passage disposed at a second distal end of the cannula where the cannula is connected to a second source of ventilation gas, and the second and third portions of the input gas flow passage are disposed at an obtuse angle to one another." Additionally, the Strickland patent fails to teach or suggest Applicants' claimed first, second and third portions of the inflow passage being disposed at an obtuse angle to one another. In particular, and as acknowledged by the

<sup>1</sup> See Strickland et al, column 3, lines 34-44 and Fig. 5, items 50 and 51.

<sup>2</sup> See MPEP 2131: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference," (Citations omitted) (emphasis added). See also MPEP 2143.03: "All words in a claim must be considered in judging the patentability of that claim against the prior art."

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outstanding Office Action,<sup>3</sup> the Strickland et al. patent fails to teach or suggest the claimed obtuse angles between the first portion of the device and the second and third portions of the device.

The outstanding Office Action rejects Applicants' Claims 2, 6, 10, 12, 13, 19, 32 and 33 based on the proposition that it would have been an obvious matter of design consideration to modify Strickland to obtain the invention as specified in those claims. The Office Action further states the Applicant has not disclosed that having the first, second and third portions of the input gas flow passage at an obtuse angle provides an advantage, is used for a particular purpose, or solves any stated problem and that one of ordinary skill in the art would have expected Applicant's invention to perform equally well with the first, second, and third portions of the input gas flow at any angle as long as there was laminar flow. However, there is no evidence that a person of ordinary skill in the art would be motivated to perform such changes and redesign. Applicant's invention cites the goal of providing improved laminar flow in Paragraphs [0013], [0039], [0053], and [0056]. Specifically, paragraph [0039] states "the cannula body 303 can extend along the one or more axes such that laminar flow can be achieved between the second portion 123 of the input gas flow passage and portions of the input gas flow passage upstream and/or downstream of the second portion, and/or can extend along the one or more axes such that laminar flow can be achieved between the fourth portions 153 and the second portions 123 of the output gas flow passage." Additionally, paragraph [0053] states, "laminar flow is achieved among and/or within one or more of the portions (i.e., the first through fifth portions) of the input gas flow passage of the first ventilation interface 100 is achieved among and within all of the portions of the input

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<sup>3</sup> See outstanding Office Action at page 7.

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gas flow passage." Further, paragraph [0056] states, "the ventilation interface system according to the exemplary embodiments of the present invention can provide the ventilation gas from the ventilation source to the nares at a lower velocity as compared to the conventional ventilation interface, thereby decreasing an amount of moisture removed from the mucosal walls." Accordingly, Applicants respectfully traverse, and request reconsideration of, this rejection based on these patents.<sup>4</sup>

### 103: Closing

In rejecting a claim under 35 U.S.C. 103(a), the USPTO must support its rejection by "substantial evidence" within the record,<sup>5</sup> and by "clear and particular" evidence<sup>6</sup> of a suggestion, teaching, or motivation to combine the teachings of different references. As discussed above, there is no substantial evidence, nor clear and particular evidence, within the record of motivation for modifying the Strickland et al. device by incorporating obtuse angles between a first portion of the device and the second and third portions of the device. Without such motivation and absent improper hindsight reconstruction,<sup>7</sup> a person of ordinary skill in the art would not be motivated to

<sup>4</sup> See MPEP 2142 stating, as one of the three "basic criteria [that] must be met" in order to establish a *prima facie* case of obviousness, that "the prior art reference (or references when combined) must teach or suggest all the claim limitations," (emphasis added). See also MPEP 2143.03: "All words in a claim must be considered in judging the patentability of that claim against the prior art."

<sup>5</sup> *In re Gartside*, 203 F3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000) (holding that, consistent with the Administrative Procedure Act at 5 USC 706(e), the CAFC reviews the Board's decisions based on factfindings, such as 35 U.S.C. 103(a) rejections, using the substantial evidence standard because these decisions are confined to the factual record compiled by the Board.)

<sup>6</sup> *In re Dembiczak*, 175 F3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) ("We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, although the suggestion more often comes from the teachings of the pertinent references.' The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular." (emphasis added).

<sup>7</sup> See MPEP 2141, stating, as one of the tenets of patent law applying to 35 USC 103, that "[t]he references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention."

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perform the proposed modification, and Claims 2, 6, 10, 12, 13, 19, 32 and 33 are believed to be non-obvious and patentable over the applied prior art.

### CONCLUSION

The present amendment is submitted in accordance with the provisions of 37 C.F.R. 1.116, which after Final Rejection permits entry of amendments placing the claims in better form for consideration on appeal. As the present amendment is believed to overcome outstanding rejections under 35 U.S.C. §112, first paragraph, 35 U.S.C. §102 and 35 U.S.C. §103, the present amendment places the application in better form for consideration on appeal. In addition, the present amendment is not believed to raise new issues since the changes to Claims 1, 28 and 30 are supported by the specification and figures and the change to Claim 2 is of a minor nature. It is therefore respectfully requested that 37 C.F.R. 1.116 be liberally construed, and that the present amendment be entered.

Consequently, in view of the present amendment, no further issues are believed to be outstanding in the present application, and the present application is believed to be in condition for formal Allowance. A Notice of Allowance for Claims 1-23, 28 and 30-33 is earnestly solicited.

Should the Examiner deem that any further action is necessary to place this application in even better form for allowance, the Examiner is encouraged to contact Applicant's undersigned representative at the below listed telephone number.

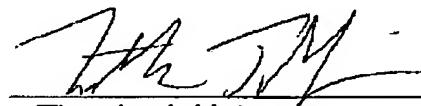
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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 50-3136 and please credit any excess fees to such deposit account.

Respectfully submitted,



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**Date: October 20, 2005**

Attachment(s):